CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76175

CORRESPONDENCE

JUN 27 2001

Geneva Pharmaceuticals Technology Corporation
Attention: Mahendra Patel, Ph.D.
2400 Route 130 North
Dayton, NJ 08810

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to your correspondence dated June 7, 2001.

NAME OF DRUG: Mefloquine Hydrochloride Tablets, 250 mg

DATE OF APPLICATION: May 23, 2001

DATE (RECEIVED) ACCEPTABLE FOR FILING: May 24, 2001

You have filed a Paragraph IV patent certification, in accordance with 21 CFR 314.94(a)(12)(i)(A)(4) and Section 505(j)(2)(A)(vii)(IV) of the Act. Please be aware that you need to comply with the notice requirements, as outlined below. In order to facilitate review of this application, we suggest that you follow the outlined procedures below:

CONTENTS OF THE NOTICE

You must cite section 505(j)(2)(B)(ii) of the Act in the notice and should include, but not be limited to, the information as described in 21 CFR 314.95(c).

SENDING THE NOTICE

In accordance with 21 CFR 314.95(a):

- Send notice by U.S. registered or certified mail with return receipt requested to each of the following:

  1) Each owner of the patent or the representative designated by the owner to receive the notice;

2) The holder of the approved application under section 505(b) of the Act for the listed drug claimed by the patent and for which the applicant is seeking approval.

3) An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.

DOCUMENTATION OF NOTIFICATION/RECEIPT OF NOTICE

You must submit an amendment to this application with the following:

- In accordance with 21 CFR 314.95(b), provide a statement certifying that the notice has been provided to each person identified under 314.95(a) and that notice met the content requirements under 314.95(c).

- In accordance with 21 CFR 314.95(e), provide documentation of receipt of notice by providing a copy of the return receipt or a letter acknowledging receipt by each person provided the notice.

- A designation on the exterior of the envelope and above the body of the cover letter should clearly state "PATENT AMENDMENT". This amendment should be submitted to your application as soon as documentation of receipt by the patent owner and patent holder is received.

DOCUMENTATION OF LITIGATION/SETTLEMENT OUTCOME

You are requested to submit an amendment to this application that is plainly marked on the cover sheet "PATENT AMENDMENT" with the following:

- If litigation occurs within the 45-day period as provided for in section 505(j)(4)(B)(iii) of the Act, we ask that you provide a copy of the pertinent notification.

- Although 21 CFR 314.95(f) states that the FDA will presume the notice to be complete and sufficient, we ask that if you are not sued within the 45-day period, that you provide a letter immediately after the 45 day period elapses, stating that no legal action was taken by each person provided notice.

- You must submit a copy of a court order or judgement or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information. We ask that this information be submitted promptly to the application.

If you have further questions you may contact Gregg Davis, Chief, Regulatory Support Branch, at (301) 827-5862.

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Tim Ames
Project Manager
(301) 827-5848

Sincerely yours,

/S/

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 76-175
DUP/Jacket
Division File
Field Copy
HFD-610/R.West
HFD-610/P.Rickman
HFD-92
HFD-615/M.Bennett
HFD-600/

Mahendra Patel, Ph.D
Chief Scientific Officer

Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810
Tel 732 274 2400
Fax 732 274 8989

Geneva
PHARMACEUTICALS

6/20/01 ACK for filing S. Middleton 6/20/01

Concur. 27-JUN-2001 Gregory B Davis

May 23, 2001

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

ORIGINAL ANDA SUBMISSION

CENTER FOR DRUG EVALUATION AND RESEARCH
RECEIVED
MAY 24 2001
OGD

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**

Dear Sirs:

I have herewith enclosed the original Abbreviated New Drug Application (ANDA) document for ***MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg.*** The ANDA application contains the following documents:

1. Archival Copy — 12 volumes
2. Review Copy
   Chemistry, Manufacturing and Controls — 3 volumes
3. Review Copy
   Bioavailability/Bioequivalence — 9 volumes
   (Hard copy of Raw Data with a copy of raw data on 3½" disk, attached to the inner cover)
4. Two additional separately bound copies of **Section 15 (Controls for the Finished Dosage Form)** and **Section 16 (Analytical Methods)**, as the drug substance and drug product are not compendia article(s); (2 Sets, volume(s) 1 of 2 and 2 of 2 each).

The drug substance MEFLOQUINE HYDROCHLORIDE and drug product MEFLOQUINE HYDROCHLORIDE TABLETS are not compendia articles. The firm provides a commitment that they will cooperate with the agency to resolve any issues related to Method Validation as provided in this application.

Please note that the listed drug LARIAM TABLETS, 250 mg, manufactured by F. Hoffmann-La Roche Ltd., as referenced in this application has an approved NDA 019591 with the Food and Drug Administration.

Please note that Invamed Inc. was acquired by Geneva Pharmaceuticals, Inc., on December 8, 1999. Pursuant to this acquisition, Invamed Inc., was assigned a new name viz. Geneva Pharmaceuticals Technology Corporation (abbreviated as GPTC) as a separate corporation. Please note that documentation provided herein may contain the old name in some of the sections.

The firm has submitted an additional copy of the Technical Section [as required under 314.50 (d) (1)] to the U.S. Food & Drug Administration, New Jersey District Office. We hereby certify that this additional copy (field copy) is a true copy of the Technical Section as described in § 314.94 (a) (9) contained in the Archival and Review copies of the abbreviated application.

Sincerely,

Mahendra Patel, Ph.D.
Chief Scientific Officer

Pankaj Dave, Ph.D
Director, Regulatory Affairs

Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 8989

Geneva
PHARMACEUTICALS

July 11, 2001

Ms. Krista Scardina
Project Manager
Division of Bioequivalence
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

TELEPHONIC BIO AMENDMENT

ORIG AMENDMENT

AB

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**
ANDA # 76-175

Dear Ms. Scardina:

In reference to your telephonic conversation of July 10, 2001, I am herewith submitting the ***"Telephonic Bio Amendment"*** document for our pending Abbreviated New Drug Application (ANDA # 76-175) for ***MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg.***

The firm is providing dissolution data on the reference and test drug product (12 tablets each) in accordance with the test procedure recommended by the Division of Bioequivalence. The dissolution profile study was performed with the following test conditions:

Media:	900 mL Simulated Gastric Fluid without enzyme at 37° ± 0.5°C
Apparatus:	USP <current>, Apparatus 1 (Basket)
RPM:	100
Sampling Interval:	15, 30, 45 and 60 minutes

Please provide appropriate Q specifications if this method needs to be incorporated in firm's release and stability controls. The firm will provide a copy of updated analytical procedure with recommended dissolution method and specification indicating implementation of proposed control.

Sincerely,

Pankaj Dave, Ph.D.

CENTER FOR DRUG
RECD
JUL 12 2001
OGD
EVALUATION AND RESEARCH

Pankaj Dave, Ph.D
Director, Regulatory Affairs

Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 8989

Geneva
PHARMACEUTICALS

July 11, 2001

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

NEW CORRESP

Re: **ANDA # 76-175**
MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg
Copies for Chemistry Archival and Review Jackets

Dear Sirs:

The firm submitted a response to a Telephonic Bio Amendment on July 11, 2001 to Ms. Krista Scardina, Project Manager, Division of Bioequivalence, FDA.

I have herewith attached a copy of the same (in duplicate) for your Chemistry and Archival review.

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
JUL 12 2001
OGD

Sincerely,

Pankaj Dave, Ph.D.

Mahendra Patel, Ph.D
Chief Scientific Officer

Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 1040

Geneva
PHARMACEUTICALS

PATENT AMENDMENT

July 2, 2001

NC
NEW CORRESP

Emily Thomas
NDA I
7/11/01

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**
ANDA# 76-175

Dear Sirs:

As required under 21 CFR 314.95(b), please note that we are certifying that a patent non-infringement notification has been provided to each person identified under 314.95 (a) and the notice meets the content requirement as described under 314.95(c) for our pending Abbreviated New Drug Application (ANDA) # 76-175 for **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg.**

Please note that this notification was received by Hoffman-La Roche Inc., on June 12, 2001. A copy of relevant documentation for the receipt of this document, as required pursuant to 21 CFR 314.95(e), is provided for ease of review.

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
JUL 03 2001
CGD

Sincerely,

M. A. Patel

Mahendra Patel, Ph.D.
Chief Scientific Officer

cc: Mr. Jeremiah McIntyre
Geneva Pharmaceuticals, Inc.,
2655 W. Midway Blvd.,
Broomfield, CO 80038-0446.

Pankaj Dave, Ph.D
Director, Regulatory Affairs

Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 8989

Geneva
PHARMACEUTICALS

October 12, 2001

ORIG AMENDMENT
N/A M

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

MINOR AMENDMENT

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**
ANDA # 76-175

Dear Sirs:

I have herewith enclosed a "*MINOR AMENDMENT*" document submitted in duplicate for our pending application for ***MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg*** **(ANDA # 76-175)** as required under 21 CFR 314.120.

Additionally, the firm is also submitting a duplicate set of any addendum to the previously submitted analytical method validation report(s) as well as other specification changes referenced as a part of this submission.

The firm has submitted an additional copy of this MINOR AMENDMENT to the U.S. Food and Drug Administration, New Jersey District Office. We hereby certify that this additional copy (field copy) is a true copy of the Archival and Review copies of the MINOR AMENDMENT.

Sincerely,

Pankaj Dave, Ph.D.

CENTER FOR DRUG
OCT 15 2001
EVALUATION AND RESEARCH

10/18/01

Mahendra Patel, Ph.D
Chief Scientific Officer

Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 8989

Geneva
PHARMACEUTICALS

Emily Thomas
NDA I
8/6/01
not sued on
PIV for '855

July 30, 2001

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

PATENT AMENDMENT

NEW CORRESP

NC

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**
ANDA # 76-175

Dear Sirs:

On June 7, 2001, Geneva Pharmaceuticals Technology Corporation ("Geneva") sent the following documentation to Hoffman La-Roche Inc., in connection with Geneva's **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg ANDA# 76-175**: a Certified Mail Receipt letter asserting non-infringement with respect to U.S. Patent No. 4,579,855 (the "855 Patent") together with a detailed statement of the factual and legal basis for Geneva's position that its Mefloquine product does not infringe U.S. Patent No. 4,579,855 (the "855 Patent").

This notice was received by Hoffman La-Roche Inc., on June 12, 2001.

Documentation towards this notification (a copy of letter sent to Hoffman La-Roche Inc., dated June 7, 2001, proof of mailing by U.S. Postal Service and receipt of the same by Hoffman La-Roche Inc., on June 12, 2001) was submitted to the agency on July 2, 2001.

A 45-day review period pursuant to the submission and receipt of the notice by Hoffman La-Roche Inc., expired on July 26, 2001. Please note that Geneva has not been sued by Hoffman La-Roche Inc., in reference to the Paragraph IV Certification for the patent 4,579,855 (expiring on October 01, 2004).

The firm is therefore requesting the agency to grant a full approval of the above referenced application prior to the expiration of the above patent contingent upon satisfactory completion of review at the Center.

CENTER FOR DRUG
RECD
JUL 31 2001
OGD
EVALUATION AND RESEARCH

Geneva
PHARMACEUTICALS

Please confirm if the Office of Generic Drugs has received any information from Hoffman La-Roche Inc., contrary to this matter.

Sincerely

M. D. Patel

Mahendra Patel, Ph.D.
Chief Scientific Officer

Pankaj Dave, Ph.D
Director, Regulatory Affairs

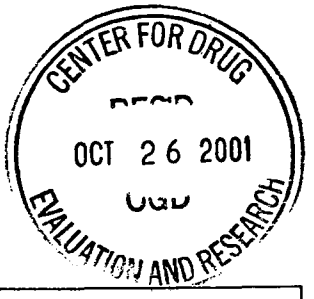
Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 8989

Geneva
PHARMACEUTICALS

N/A

October 25, 2001



Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

TELEPHONE AMENDMENT

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**
ANDA # 76-175

Dear Sirs:

I have herewith enclosed a "*TELEPHONE AMENDMENT*" document submitted in duplicate for our pending application for ***MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg*** **(ANDA # 76-175)** as required under 21 CFR 314.120.

Reference is made here to a telephonic conversation of October 25, 2001, between Dr. Ramesh Sood, Dr. James Fang and Ms. Sarah Ho of Office of Generic Drugs, FDA, and Dr. Pankaj Dave and Dr. Sudhakar Rao of GPTC.

As recommended, the firm has revised the specification for Impurity I to Not More Than % and Total Impurities to Not More Than % for initial release as well as monitoring of on-going stability studies of the finished dosage form. The firm is providing following documents indicating implementation of this change control:

1. A copy of Product Specifications and Release Report.
2. A copy of Analytical Test Procedure for the finished dosage form.
3. A copy of amended stability protocol for the exhibit batch.
4. A copy of amended stability protocol for the proposed production batch.

Additionally, the firm is also submitting a duplicate set of any addendum to the previously submitted documents as well as other specification changes referenced as a part of this submission.

As recommended, a desk copy of this submission is faxed to the attention of Ms. Sarah Ho and also to the Document Control Room. Additionally, the hard copy document submission is sent out by overnight courier service.

Geneva
PHARMACEUTICALS

The firm has submitted an additional copy of this amendment to the U.S. Food and Drug Administration, New Jersey District Office. We hereby certify that this additional copy (field copy) is a true copy of the Archival and Review copies of this submission.

Sincerely,

Pankaj Dave, Ph.D.

Pankaj Dave, Ph.D
Director, Regulatory Affairs

Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 8989

Geneva
PHARMACEUTICALS

ORIG AMENDMENT
N/AF

October 26, 2001

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

LABELING AMENDMENT

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**
ANDA # 76-175

Dear Sirs:

I have herewith enclosed a "*LABELING AMENDMENT*" response document submitted in duplicate for our pending application for ***MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg*** **(ANDA # 76-175)** as required under 21 CFR 314.120.

Sincerely,

Pankaj Dave, Ph.D.

Pankaj Dave, Ph.D
Director, Regulatory Affairs

Geneva Pharmaceuticals
Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 8989

Geneva
PHARMACEUTICALS

November 5, 2001

N/AF

ORIG AMENDMENT

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

LABELING AMENDMENT

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**
ANDA # 76-175

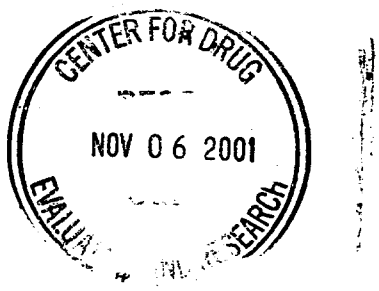
Dear Sirs:

I have herewith enclosed a "*LABELING AMENDMENT*" response document submitted in duplicate for our pending application for ***MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg*** **(ANDA # 76-175)** as required under 21 CFR 314.120.

This submission provides twelve (12) each of the Final Printed Labeling components for insert labels; final cut outs for carton labels and unit-dose blister card labels respectively.

Sincerely,

Pankaj Dave, Ph.D.



Geneva
PHARMACEUTICALS

Mahendra Patel, Ph.D
Chief Scientific Officer

Geneva Pharmaceuticals Technology Corporation
2400 Route 130 North
Dayton, NJ 08810

Tel 732 274 2400
Fax 732 274 8989

10/26/01 NAI. PIV Cert. Change from III cert. S. Middleton

Concur. 27-JUN-2001 Gregory E. Davis

June 7, 2001

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

PATENT
AMENDMENT
NEW CORRESP
NC

Re: **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg**
ANDA # 76-175

Dear Sirs:

I have herewith enclosed (in duplicate) an amended Patent Certification for the above referenced Abbreviated New Drug Application (ANDA) for **MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg (ANDA # 76-175).**

Please note that through this amendment the firm is submitting a Paragraph IV Certification with respect to US Patent 4,579,855 for the reference listed drug product.

Sincerely,

M. N. Patel

Mahendra Patel, Ph.D.
Chief Scientific Officer

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
JUN 0 8 2001
OGD

Desk Copy to: Mr. Martin Shimer, FDA – Via Fax

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
GENEVA PHARMACEUTICALS TECHNOLOGY CORPORATION	06/07/01
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE (FAX) Number** (Include Area Code)
732-274-2400	732-274-1040
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE
2400 Rt. 130 N DAYTON, NJ 08810	NOT APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 76-175

ESTABLISHED NAME (e.g., Proper name, USP/USAN name)	PROPRIETARY NAME (trade name) IF ANY
MEFLOQUINE HYDROCHLORIDE	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any) (R*,S*)-(±)- α-2--Piperidinyl-2,8-bis (trifluromethyl)-4-quinolinemethanol hydrochloride

CODE NAME (If any) NONE

DOSAGE FORM: TABLET	STRENGTHS: 250 mg	ROUTE OF ADMINISTRATION: ORAL

(PROPOSED) INDICATION(S) FOR USE: TREATMENT OF ACUTE MALARIA INFECTIONS

APPLICATION INFORMATION

'LICATION TYPE
ack one)
☐ NEW DRUG APPLICATION (21 CFR 314.50) ☒ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug LARIAM TABLETS, 250 mg Holder of Approved Application ROCHE

TYPE OF SUBMISSION
(check one)
☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION SUBMISSION OF AMENDED PATENT CERTIFICATION TO PARAGRAPH IV

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current 'cation)

This application contains the following items: *(Check all that apply)*		
☐	1. Index	
☐	2. Labeling *(check one)*	☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50(c))	
☐	4. Chemistry section	
☐	A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50(d) (1), 21 CFR 601.2)	
☐	B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)	
☐	C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)	
☐	5. Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)	
☐	6. Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)	
☐	7. Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))	
☐	8. Clinical data section (e.g. 21 CFR 314.50 (d) (5), 21 CFR 601.2)	
☐	9. Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)	
☐	10. Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)	
☐	11. Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)	
☐	12. Case report forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)	
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))	
☒	14. A patent certification with respect to any patent which claims the drug (21 U.S.C.355 (b) (2) or (j) (2) (A)	
☐	15. Establishment description (21 CFR Part 600, if applicable)	
☐	16. Debarment certification (FD&C Act 306 (k) (1))	
☐	17. Field copy certification (21 CFR 314.50(k) (3))	
☐	18. User Fee Cover Sheet (Form FDA 3397)	
☐	19. OTHER (Specify)	

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been review and, to the best of my knowledge are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
M. R. Patel	MAHENDRA PATEL, Ph.D. CHIEF SCIENTIFIC OFFICER	06/07/01

ADDRESS *(Street, City, State, and ZIP Code)*	TELEPHONE NUMBER
2400 RT. 130, DAYTON, NJ 08810	732-274-2400

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestionsfor reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
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Geneva
PHARMACEUTICALS

SECTION 3 **AMENDED PATENT AND EXCLUSIVITY CERTIFICATION:**

Date: June 7, 2001
Name of Applicant: Geneva Pharmaceuticals Technology Corporation
Address of Applicant: 2400 Route 130, Dayton, NJ 08810
Drug: MEFLOQUINE HYDROCHLORIDE TABLETS, 250 mg

(1) **PATENT CERTIFICATION STATEMENT**

Geneva Pharmaceuticals Technology Corporation ("Geneva"), by this ANDA, is requesting approval for mefloquine 250 mg tablets ("the Geneva Product"). Upon information and belief, Geneva believes that Hoffmann La-Roche Inc. ("Roche") is the holder of the NDA for the listed drug product identified above.

Geneva hereby certifies that, upon information and belief, U.S. Patent No. 4,579,855 has been listed in Approved Drug Products as covering Roche's Lariam™ brand mefloquine product.

PARAGRAPH IV CERTIFICATION FOR U.S. PATENT NO. 4,579,855

Geneva submits the following certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) with respect to U.S. Patent No. 4,579,855:

Geneva certifies that the claims of U.S. Patent No. 4,579,855 are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the mefloquine tablets for which this application is submitted.

Geneva will comply with the requirements of 21 C.F.R. §314.95(a) with respect to providing a notice to each patent owner, or their representatives, and to the holder of the approved application for the listed drug, and with the requirements of 21 C.F.R. §314.95(c) with respect to the content of the notice.

(2) GPTC hereby certifies that to the best of its knowledge there are no exclusivities associated with the Approved Listed Drug Product, LARIAM TABLETS 250 mg.

M.P.

Mahendra Patel, Ph.D.
Chief Scientific Officer

Reference: Electronic Orange Book; Updated: April 16, 2001